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(54) MAMMOGRAPHY INFORMATION SYSTEM

(75) Inventor: Greg Gustafson, Maple Plain, MN (US)

(73) Assignee: PENRAD TECHNOLOGIES, INC.,

Buffalo, MN (US)

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U.S.C. 154(b) by 667 days.

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(Continued)

(52) U.S. Cl.

(58) **Field of Classification Search** CPC G06T 7/0012; G06Q 50/22; G06Q 50/24;

See application file for complete search history.

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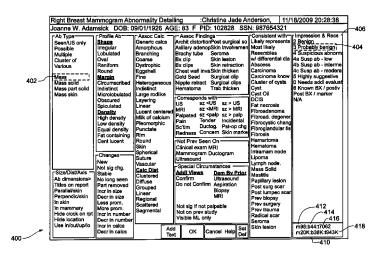
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Primary Examiner — Luke Gilligan (74) Attorney, Agent, or Firm — Patterson Thuento Pedersen, P.A.

(57) ABSTRACT

A method and system for analyzing and retrieving breast tissue abnormality tracking data, providing a tool for a radiologist that includes a report summarizing the statistical frequency of diagnosed patients, both locally and nationally, with breast tissue region-of-interest classifications similar to the breast tissue images taken of the anatomy of an individual patient. In one embodiment, a computer aided diagnostic program can be tested or verified against the breast tissue images and the region-of-interest classifications that have been validated by definitive patient diagnosis. Another embodiment allows the efficient collection of all of the breast tissue abnormalities for a given medical facility in order to provide trending data or radiologist performance analysis. In yet another embodiment, the region-of-interest abnormalities in a single location in a patient's tissue are correlated across a variety of imaging modalities including X-rays, mammogram, CT, ultrasound, MRI, or other imaging technologies. In another embodiment, the region-of-interest feature descriptors based on a location of an abnormality can be correlated by features and images for a plurality of imaging modalities as well as the pathological outcome.

16 Claims, 21 Drawing Sheets



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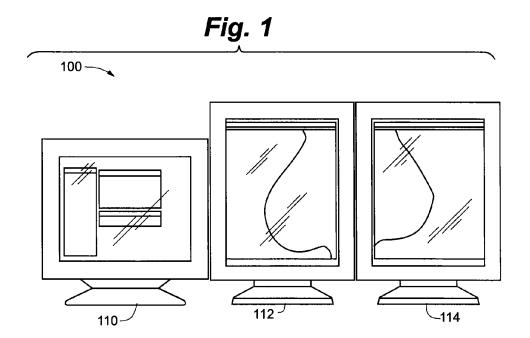
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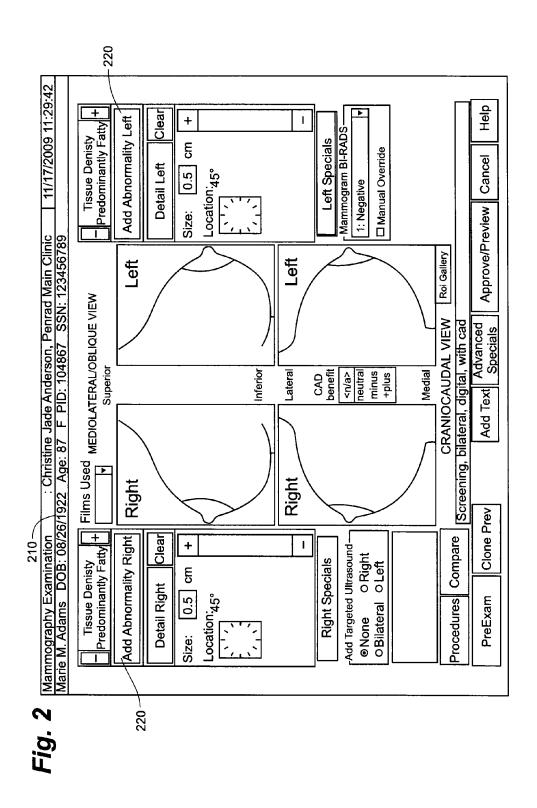
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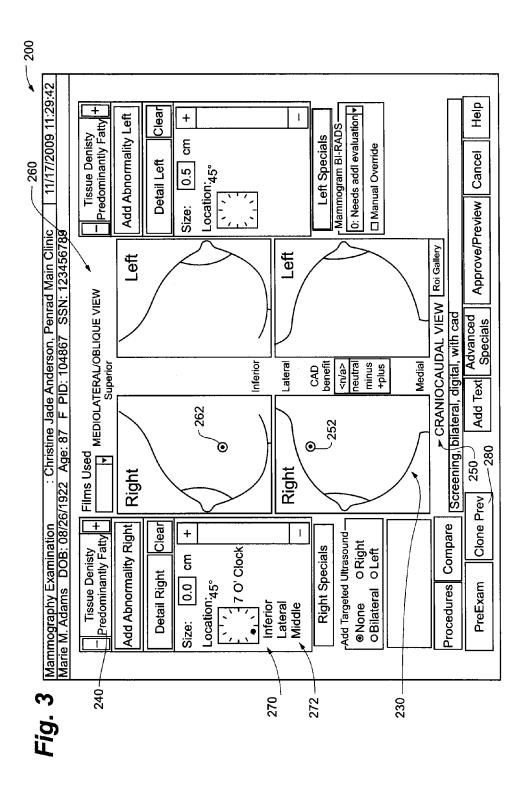
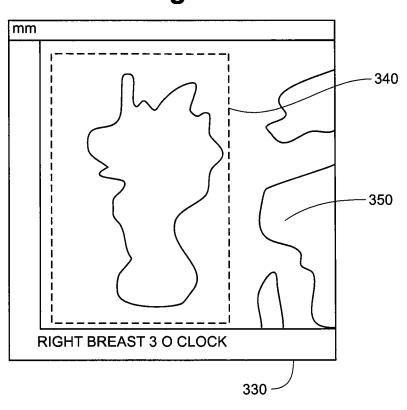
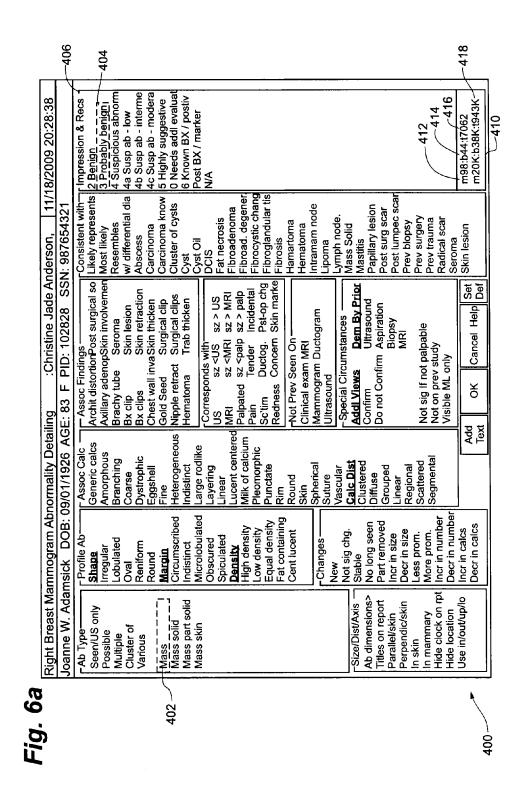


Fig. 4 -310 320 300

Fig. 5





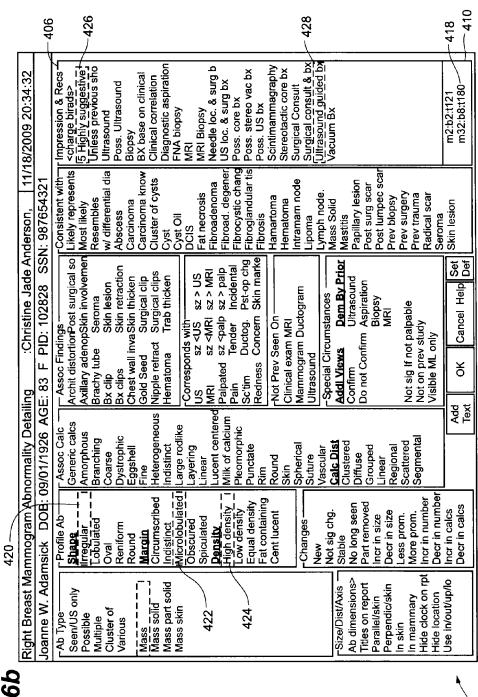
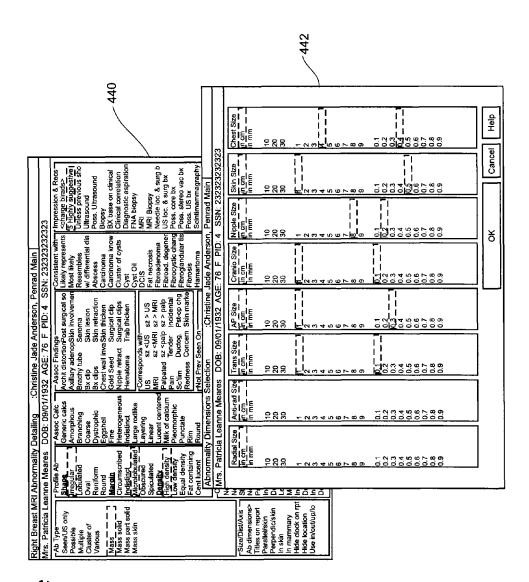
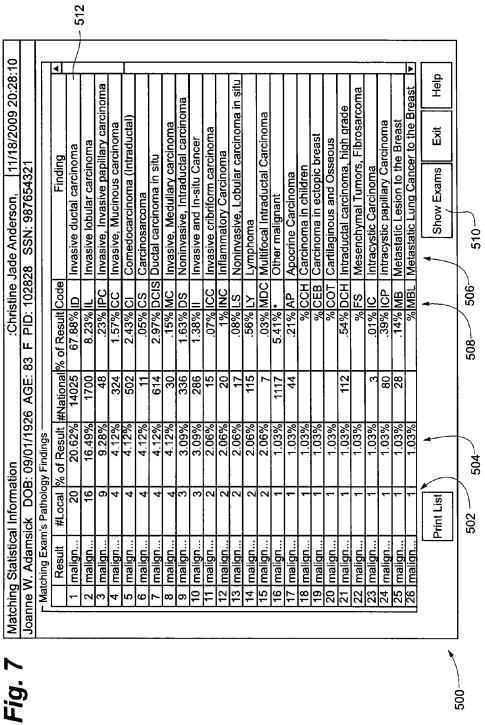
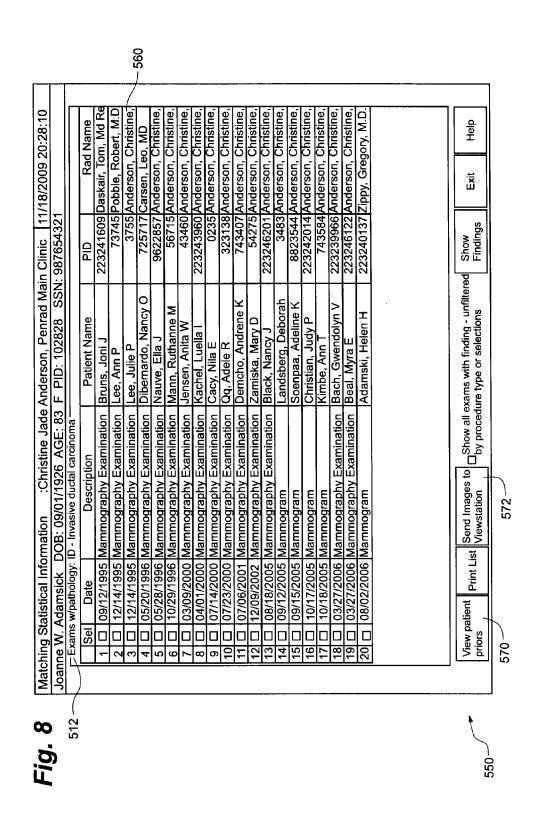


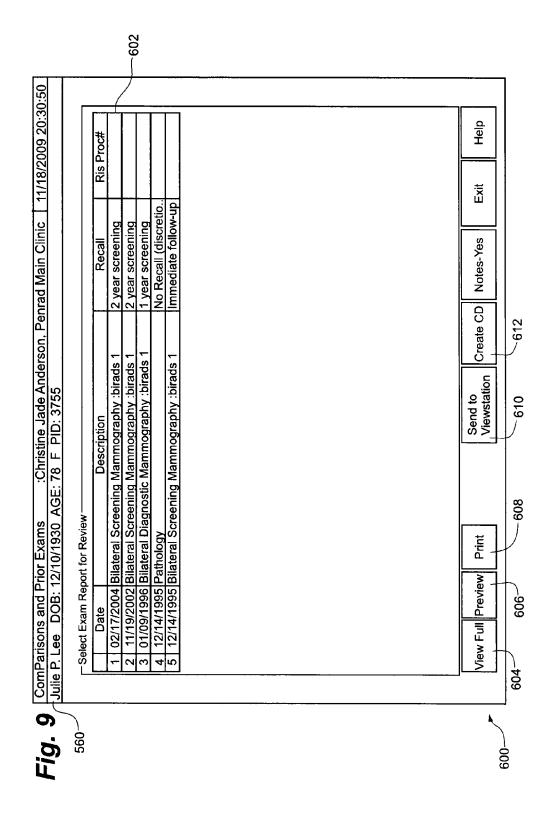
Fig. 6b





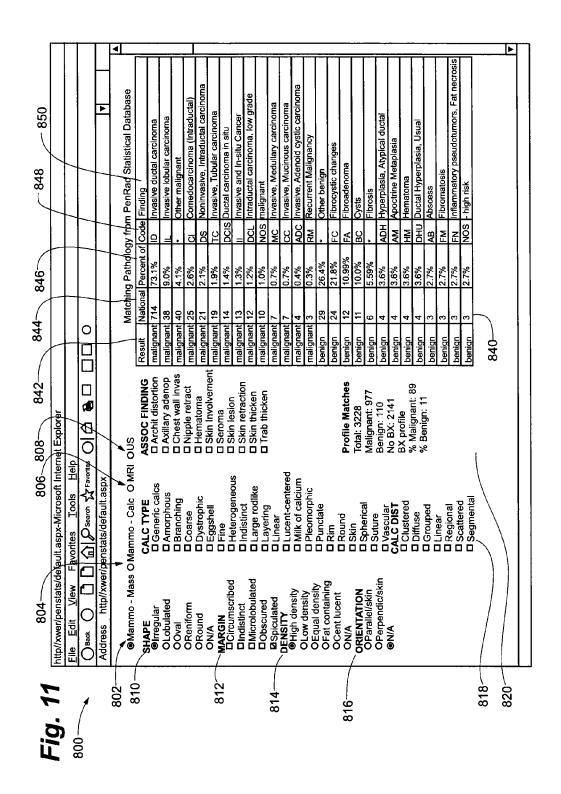
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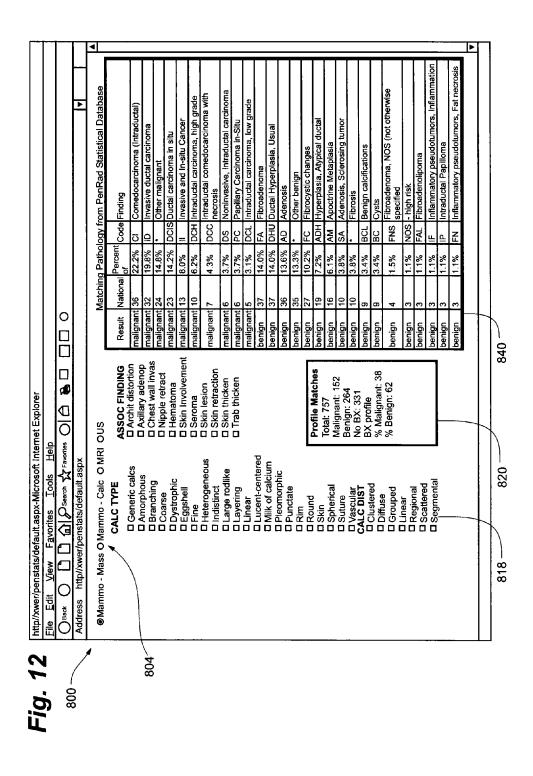


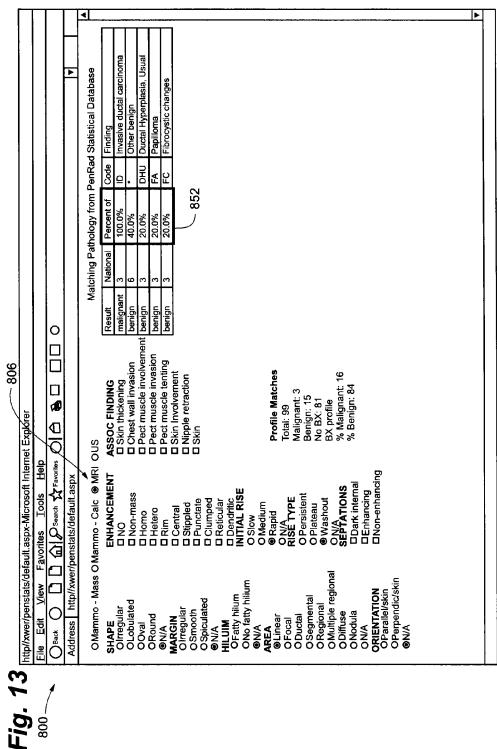
11/18/2009 20:33:23 There is a 6 cm round high density mass with a spiculated margin in the right breast at 12 o'clock in the posterior depth The mass in the right breast is suspicious of malignancy. A clinical correlation is recommended for the mass. Close REPORT REFLECTS CURRENT DEMOGRAPHICS AND CODING OS OF 11/18/2009 as palpated. Compared to previous films, this mass is new. No significant masses, calcifications, or other findings are seen in the left breast. IMPRESSIONS: SUSPICIOUS OF MALIGNANCY Imaging Technologist: Rabbi Patty A. Ferdickson RT(R)(M), Penrad Main Clinic :Christine Jade Anderson, Penrad Main Clinic Comparison is made to exam dated: 4/24/1993 East Memorial Center. Julie P. Lee DOB: 12/10/1930 AGE: 78 F PID: 3755 Print Copy BILATERAL SCREENING MAMMOGRAM: 12/14/1995 The tissue of both breasts is predominantly fatty. letter sent: Biopsy Required Mammo BI-RADS: 4 Suspicious abnormality The patient has been or will be contacted. Dr. Christine Jade Anderson M.D. cja/penrad:12/14/1995 13:17:57 Golden Valley, Minnesota 55343 Fax: (763) 555-5555 Preview

Fig. 10



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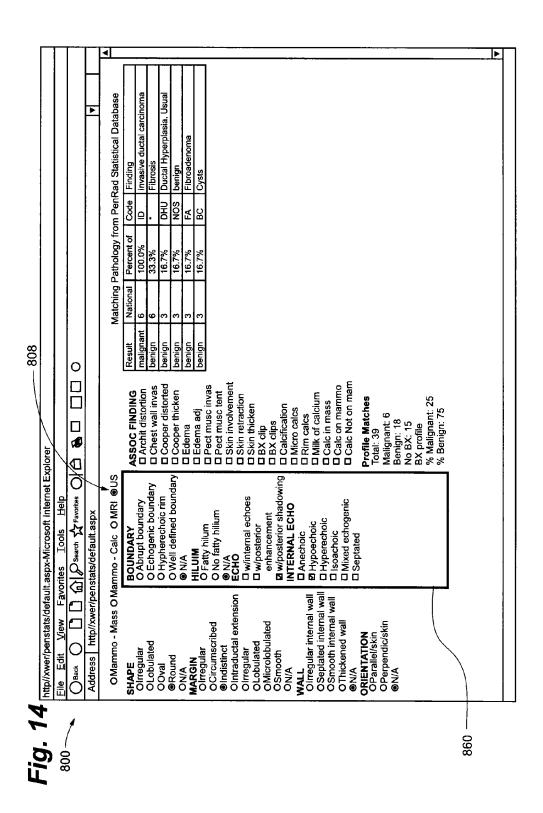
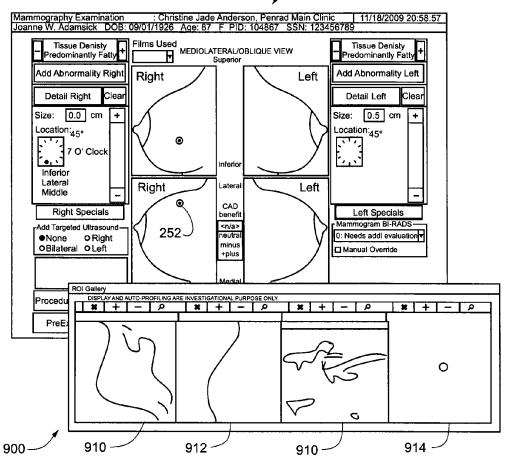
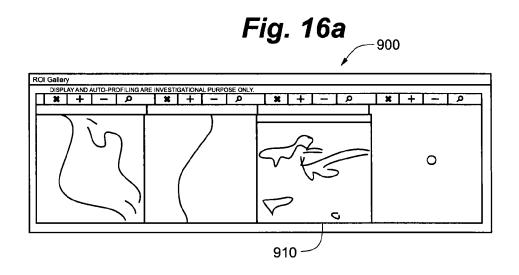
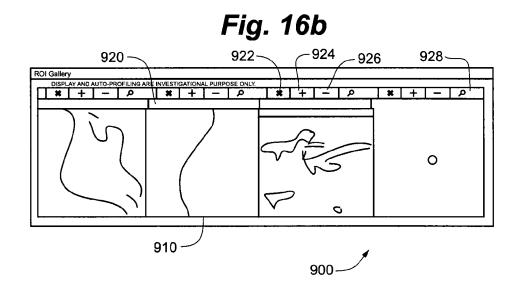
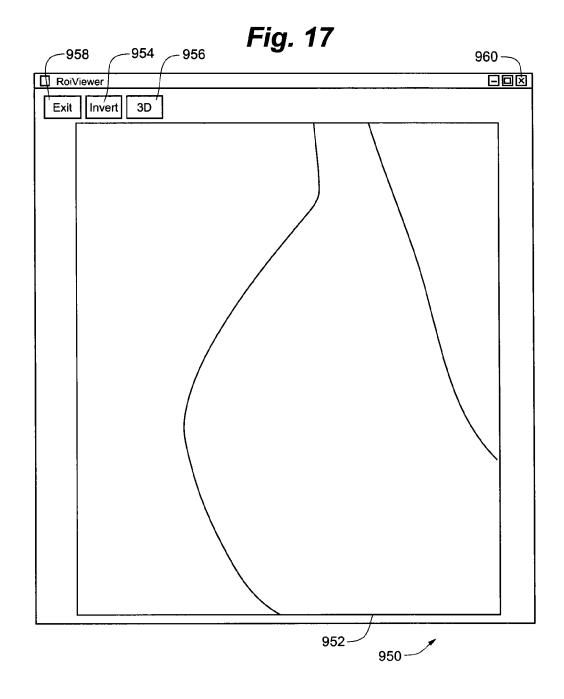


Fig. 15









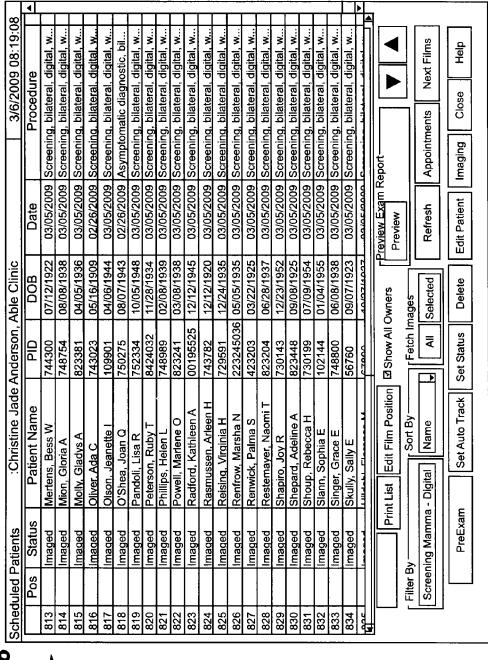
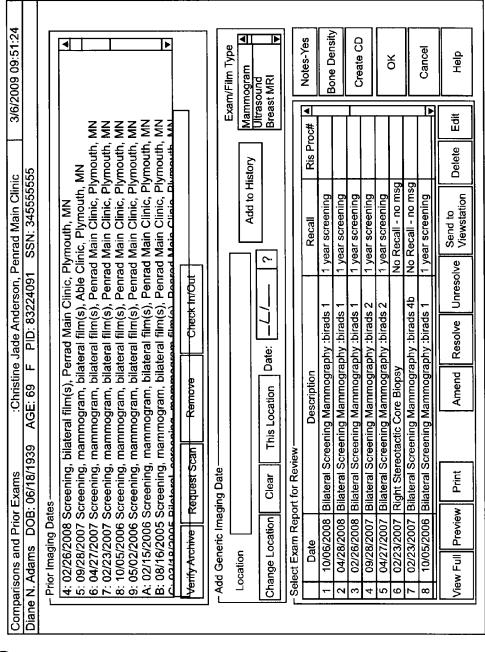


Fig. 18

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1

MAMMOGRAPHY INFORMATION SYSTEM

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional ⁵ Application No. 61/282,000, entitled "MAMMOGRAPHY INFORMATION SYSTEM" and filed Nov. 24, 2009, which is incorporated herein by reference in its entirety.

The following co-pending patent applications of common assignee contain some common disclosure: "Multiple 10 Modality Mammography Image Gallery and Clipping System," and "Mammography Statistical Diagnostic Profiler and Prediction System," filed Nov. 25, 2009, having Ser. Nos. 12/625,926 and 12/625,910, respectively, which are incorporated herein by reference in their entireties. A copy of each of 15 the above-identified related applications is attached hereto as Appendix A and Appendix B, respectively.

TECHNICAL FIELD

The invention relates to management of medical data and more specifically to patient data and breast tissue images originating from multiple modalities.

BACKGROUND OF THE INVENTION

Historically, interpretation and diagnosis of mammograms and other medical image analysis has been performed using hardcopy x-ray films viewed on an alternator that typically allows x-ray films to be illuminated and masked for diagnostic viewing. Newer technology allows a radiologist or other medical professional to view mammograms and other diagnostic images electronically on high-resolution monitors. These images can also be digitally stored and transmitted across secure networks for archiving or review by other professionals

A radiologist generally begins his or her review process by reviewing a patient's background information relevant to a radiology study, such as a patient's name, age, and any applicable medical conditions or risk factors. After reviewing the 40 background information, the radiologist views multiple images created by radiological, X-ray, computed tomography (CT), ultrasound, magnetic resonance imaging (MRI), tomosynthesis, or other imaging technique of the patient's breast, or other organ, and dictates or uses a computerized information system to track findings, create reports, and make recommendations for future examinations. Such findings can include information pertaining to tissue density, the presence of masses, cysts, calcifications and other abnormalities, or any other breast tissue characteristics.

While there has been recent debate regarding the frequency at which women should undergo regular mammogram screenings, and at what age such screenings should begin, it is unlikely that the relatively quick and typically effective practice of mammography screening for breast cancer will disap- 55 pear completely. Accordingly, there will continue to be a need for radiologists to view and interpret the images generated from patient examinations and screenings. Because the risk of breast cancer threatens the lives of many women, especially those over age 40, radiologists are often inundated with large 60 numbers of mammogram images that must be viewed and, if abnormalities are present, categorized in order to determine if further examination is required. The developments in advanced patient imaging techniques, such as MRI, are also increasing the raw number of images that a radiologist can 65 review. Therefore, there is an ongoing need to improve the speed and efficiency of the radiologist's review of the mam2

mogram images, without sacrificing accuracy, and with the smallest number of false-positive diagnoses. Additionally, given that mammogram screenings are performed periodically, such as annually or biannually, once screening begins for a particular woman, there is also a need to manage, track and analyze data taken over a period of years or decades for that woman.

One example of a computerized mammography information system (MIS) to review patient images is the PenRad Mammography Information System available from PenRad. This system provides for the digital presentation of patient data.

Legislation has mandated that mammography facilities track positive mammography findings and correlate such findings with biopsy results, maintain statistics for mammography medical outcome and analysis audits on each physician, and provide direct written notification to all patients of their exam results. The generation and correlation of this data is maintained locally by each medical center for each patient.

One system for categorizing this information is the Breast Imaging-Reporting and Data System (BI-RADS) published by the American College of Radiology (ACR). BI-RADS provides a system of mammography assessment categories in the form of standardized codes assigned by a radiologist during or after the viewing and interpretation of a medical image. BI-RADS allows for concise and unambiguous understanding of patient records between multiple radiologists and medical facilities. Consequently, a large number of mammogram images, biopsy results, and diagnosis statistics are potentially available in a patient-anonymous format, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Recently, Digital Imaging and Communications in Medicine (DICOM) systems have become the accepted format for medical imaging systems. This format provides for the distribution and viewing of medical studies and images across a variety of platforms. The use of DICOM has, among other things, enabled industry compatibility and improved workflow efficiency between imaging and other information systems located in various healthcare environments. Currently, the DICOM standard is an 18-part publication, PS 3.1-2008 through PS 3.18-2008 describing a standard for digital imaging and communications in medicine developed by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), which is hereby incorporated by reference in its entirety. Among other elements, the DICOM standard provides a method of uniquely numbering any image or other information object to facilitate the unambiguous identification of images or information objects as they are viewed or manipulated in a system or transported across a network.

Conventional imaging systems enable a DICOM server to provide medical images across a network to various DICOM compatible clients on the network. Some examples of DICOM clients include picture archiving and communications systems, softcopy workstations, computer-aided diagnosis (CAD) systems, DICOM compatible CD or DVD burners, and other network system devices known to those skilled in the art. One example of a standards-based medical imaging environment is disclosed in U.S. Pat. No. 6,909,795, to Tecotzky et al., incorporated herein by reference.

SUMMARY OF THE INVENTION

Embodiments of the invention relate to systems and methods of retrieving and analyzing patient data in a mammography information system as part of or in conjunction with the

diagnosis and interpretation of patient mammography images that substantially meet the aforementioned needs of the industry. In an example embodiment, the system is capable of retrieving, presenting, and analyzing patent images originating from a variety of modalities.

In an embodiment, a configurable mammography diagnostic system comprises a plurality of electronic displays, at least one of the plurality of electronic displays configured to display a breast tissue image having at least one region of interest, a database including a plurality of existing categorizations of at least one known region of interest in at least one of a plurality of breast tissue images, a graphical user interface presented on at least one of the plurality of electronic displays and including an anatomical diagram on which the at least one region of interest can be marked, a detailing button linked to a screen configured to present a plurality of possible characteristics according to which a manual current categorization of a region of interest in the breast tissue image can be defined, and a profiler display button configured to present 20 statistical information related to a comparison of the manual current categorization with the existing categorizations, a clipping tool with which a portion of the breast tissue image displayed on at least one of the plurality of electronic displays can be selected as a second image, the second image display- 25 able on at least one of the plurality of electronic displays as a subset of the breast tissue image, and a processing engine configured to link the second image to the breast tissue image, store the second image in an image database, and to associate the second image with a corresponding region of interest 30 marked on the anatomical diagram.

In an embodiment, a method for managing patient mammography data comprises obtaining a plurality of breast tissue images selected from the group consisting of an X-ray image, a CT image, an MRI image, an ultrasound image, and a pathology image, identifying a region of interest in at least one of the plurality of breast tissue images, obtaining a categorization of the region of interest according to an established lexicon, comparing the categorization with a database of existing categorizations and presenting a diagnostic indicator based on the comparing, storing a selected region of the at least one of the plurality of breast tissue images as a second image, mapping the second image to a storage location of the at least one of the plurality of breast tissue images, and associating the selected region with the categorized region of 45 in mention.

FIG. 13

for use with FIG. 14

for use with for use with

In an embodiment, a mammography information system comprises at least one electronic display, a graphical user interface presented on the at least one electronic display and configured to present data and information related to a 50 patient, the graphical user interface comprising an image gallery configured to display thumbnail representations of a plurality of images that form a portion of the data and information, the plurality of images selectable from X-ray images, CT images, MRI images, ultrasound images, pathology 55 images and document images, and a database operable to store the thumbnail representations of the plurality of images.

The above summary of the invention is not intended to describe each illustrated embodiment or every implementation of the present invention. The figures and the detailed 60 description that follow more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The embodiments of the present invention may be more completely understood in consideration of the following 4

detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. 1 is an example mammogram information system (MIS) display workstation according an embodiment of the invention.

FIG. 2 is an example of a mammography exam data-form suitable for use with embodiments of the invention.

FIG. 3 is an example of the mammography exam data-form of FIG. 2 indicating a region of interest (ROI).

FIG. 4 is an example of a mammogram image with an ROI indicated.

FIG. 5 is an example of an ultrasound image with an ROI indicated.

FIG. 6a is another example embodiment of a ROI data 15 entry form for use with embodiments of the invention.

FIG. **6***b* is the ROI data entry form of FIG. **6***a* with additional ROI categorizations entered.

FIG. 6c depicts two additional exemplary embodiments of ROI data entry forms for use with embodiments of the invention

FIG. 7 is an example of a form showing the statistical analysis of a ROI.

FIG. **8** is an example of a form showing available images that match statistical analysis of the ROI of FIG. **7**.

FIG. 9 is an example of a form showing a patient's exam history.

FIG. 10 is an example embodiment of a report generated according an embodiment of the invention.

FIG. 11 is an example embodiment of a web-based form for use with an embodiment of the invention.

FIG. 12 is an example embodiment of a web-based form for use with an embodiment of the invention.

FIG. 13 is an example embodiment of a web-based form for use with an embodiment of the invention.

FIG. **14** is an example embodiment of a web-based form for use with an embodiment of the invention.

FIG. 15 is an example of a mammography exam data-form and an example of a ROI gallery window.

FIG. **16***a* is an another depiction of the ROI gallery window of FIG. **15**

FIG. **16***b* is another example of a ROI gallery window for use with embodiments of this invention.

FIG. 17 is an example embodiment of a ROI viewer depicting an individual image for use with embodiments of this invention.

FIG. 18 is an example of an interpretation work-list form for use with embodiments of the invention.

FIG. 19 is an example of a prior examinations form for use with embodiments of this invention.

While the present invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the present invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE DRAWINGS

Embodiments provide a computerized mammography information system that allows for the digital correlation of a wide variety patent data related to a mammography image or other breast tissue diagnostic imaging procedures. An exemplary system is able to electronically track breast tissue abnormalities across multiple image types, provide a customizable

interface for convenient and efficient image review, allow for an individual user to save preferred image hanging protocols, categorize multiple imaging types, generate statistics, and provide patient correspondence. Additionally, the integration of various computer aided diagnostic/detection (CAD) protocols for multiple image modalities into the system assists the medical professional in reviewing and accurately diagnosing any abnormalities present in a patient's diagnostic images. This advancement in accuracy also provides the benefit of reducing the need for expensive and invasive biopsy or surgery due to false positive diagnosis.

Embodiments of the mammography information system provide an efficient, easy to use, and customizable interface for use by a medical professional for the review and analysis of medical images from a variety of source. The system is capable of integrating medical images acquired through X-ray, CT, ultrasound, MRI, tomosynthesis, or other imaging techniques.

The increasing availability and quantity of digital information representing patient medical data and diagnostic images 20 has created a need for a system that allows a doctor or radiologist to quickly review, organize, and if necessary retrieve, multiple diagnostic images that may be indicative of an individual patient's condition. In addition to the availability of digital mammography images, other patient associated data, 25 such as biopsy or other test results and even entire medical histories or correspondence records can be stored in a digital format. Access to images where the pictured abnormality has been definitively diagnosed can assist with the doctor or radiologist's diagnosis of the new patient's individual condition. 30 Prior to the electronic production, archival, and detailed categorization of patient images, such comparisons were limited to a handful of common abnormalities described in the various medical texts or required laborious manual review of individual patient files.

Therefore, there is a need for a system that will quickly allow a radiologist to select a ROI in a mammogram or other image and correlate the ROI to a mapping or outline of the patient's anatomy in order to improve efficiency of patient diagnosis and record retrieval including a mechanism to 40 "clip" a ROI from any image modality, or form of electronic record, and associating that "clipping" with a specific ROI placement in the patient's record.

Additionally, the availability of this collection of breast tissue images and their associated biopsy results presents an 45 opportunity for statistical analysis of the likelihood that a matching region of interest (ROI) in an individual patient's mammography images is malignant or benign and whether or not a biopsy or further imaging should be ordered. Therefore, there is a need for a system that will quickly allow a radiologist to classify a ROI in a mammogram or other image and correlate the ROI to a large pool of existing data samples that have been definitively diagnosed in order to improve the accuracy and efficiency of patient diagnosis. The radiologist can be assisted in the classification of the ROI by a CAD 55 module by automatically detecting potential ROI abnormalities or simply reducing the number of physical or verbal actions needed by the radiologist to enter the ROI classifying data.

In an example embodiment, a MIS is provided for use by a 60 radiologist or other medical professional that preloads all of an individual patient's medical images for a specific portion of the patient's anatomy, regardless of the modality used to create the images. For example, in a breast cancer screening, any available x-ray, ultrasound, MRI, biopsy, or other images 65 for the patient are retrieved and preprocessed by an appropriate CAD algorithm. A CAD module for the appropriate image

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type can isolate one or more ROI for review in an individual image. The disclosed invention takes these individual CAD results and correlates any common ROI findings between images of the same or different modalities. A summary "map" or outline of the examined patient's anatomy is then generated and displayed for the medical professional along with any other details about the potential ROI(s) that were generated by the CAD module(s).

The mammography image gallery and clipping system according to the present invention provides a convenient organization of all of the images associated with a ROI, regardless of modality, for presentation to a medical professional. The system stores lower resolution clippings, or thumbnail images, for pathological images, reports, and abnormalities found, and optionally categorized, by radiologists or CAD products at a facility that have been entered into a mammography information system. The system stores low resolution images as well as the reference to the original image and ROI of the original image. As more patients are definitively diagnosed and their pathology records updated in the system, the larger the collection of abnormality images depicting a previously diagnosed and imaged condition that become available in the system. This system can be integrated into an existing MIS or utilized as a standalone interface providing access to a large sample of mammogram abnormality images.

The system also provides an efficient mechanism for creating a comprehensive collection of abnormality data. The collection comprising a uniform lexicon of classifications that allows for further analysis and study of the data while still maintaining patient privacy as required by the applicable law. Those skilled in the art of developing and maintaining electronic databases will appreciate and understand the tradeoffs associated with the storage requirements necessary for the implementation of the contemplated system. As numerous mammography facilities implement this non-patient identifying (and HIPAA compliant) data can be transferred to a central location accumulating a more complete database of abnormality images and the corresponding characterization of data points for various pathology types.

In an example embodiment, the method of analyzing and retrieving abnormality tracking data provides a report of the statistical frequency of diagnosed patients both locally and nationally with mammogram ROI classifications similar to an individual patient. The abnormality data can include information disclosing the frequency of similar ROI classifications have been biopsied and the number of biopsies that were malignant or benign. The disclosed method of capturing and reporting abnormality tracking data provides a radiologist or other medical professional a tool to assess the likelihood of a ROI being malignant or benign, and whether or not the patient should undergo additional testing. The system then presents these statistics to the radiologist who can then choose to look further into the underlying related data if he or she desires.

The statistical mammography predictive system according to the present invention provides instantly and continually updated outcome statistics to a medical professional. The system utilizes the information and data points for each and every abnormality found by radiologists at a facility that have been entered into a mammography information system. As more patients are definitively diagnosed and their pathology records updated in the system, the greater the chances that an individual patient will have a condition similar to a previously diagnosed and imaged condition. This system can be integrated into an existing MIS or utilized as a standalone interface providing access to a large sample of mammogram abnormality data.

The system also provides an efficient mechanism for creating a comprehensive collection of abnormality data. The collection comprising a uniform lexicon of classifications that allows for further analysis and study of the data while still maintaining patient privacy as required by the applicable law. 5 Only unique copies of each combination of tracing data points must be kept in the system. As duplicate data is accumulated the counters of the abnormality and its diagnosis as benign or malignant are incremented. This aggregation of data creates a compact and anonymous abnormality database for the medical location. If desired, a complete reference of all abnormality data can be maintained. Those skilled in the art of developing and maintaining electronic databases will appreciate and understand the tradeoffs associated with the storage requirements necessary for the implementation of the con- 15 templated system.

As numerous mammography facilities implement this non-patient identifying (and HIPAA compliant) data can be transferred to a central location accumulating an more complete database of abnormalities and the corresponding benign or 20 malignant counters for each combination of tracking points and pathology. Therefore, the large number of recorded abnormalities can be culled down to a manageable set of unique combinations specified by radiologists around the country. This culling, or grouping of duplicate abnormalities, 25 allows for a medical professional to access a comprehensive database of the known set of abnormalities nearly instantaneously.

In a further embodiment, the system disclosed provides a mechanism to evaluate, validate, and improve any of a variety 30 of existing CAD modules and techniques by providing an efficient platform for testing the cad module or technique against a wide variety of known, physician evaluated, and definitively diagnosed, patient abnormalities or ROI.

The invention can be better understood by reference to 35 FIGS. 1-19. FIG. 1 illustrates an example embodiment of a mammogram display workstation 100. A typical mammogram display workstation 100 includes a controller display system 110 and at least one high-resolution image monitor 112. One or more additional high-resolution image monitor 40 units 114 can also be used to provide additional viewing area to provide for the comparison of two or more images at full resolution. The controller display system 110 is any of a variety of commonly available video display monitors coupled to a personal computer such as an IBM-PC or com- 45 patible system running a version of the Microsoft WIN-DOWS operating system, or the equivalent thereof. In an embodiment, the image monitors 112 and 114 are liquid crystal displays (LCDs) that provide high-resolution and enhanced contrast for ease of viewing images, but may also be 50 a cathode ray tube or other appropriate display in other embodiments. An exemplary image monitor can display approximately 2500×2000 pixels, although a variety of image monitor sizes are contemplated. In one embodiment, the mammogram display workstation 100 includes a server com- 55 puter (not shown) that runs DICOM communications components of the mammogram display workstation 100; alternatively, this DICOM software may run on the controller display system 110. In yet another embodiment, a server computer is included that runs an Archived Image Retrieval 60 service; alternatively, this software may also run on the controller display system 110 or on the DICOM compliant server.

The mammogram display workstation 100 includes software that allows images to be analyzed using the image processor in the controller display system 110 to analyze each 65 image of a study set, compare with complementary images to generate a suspect list to reduce false indicators, and to gen-

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erate graphic overlay images to identify areas of interest. When an image is displayed on an image monitor 112 or 114, imaging tools included in the system allow a user working with the system to further manipulate an image. These software tools may provide magnification of a desired region of an image; image inversion, reversal, rotation, or other repositioning; image/background color inversion; noise filtering from images to reduce or eliminate extraneous data and enhance pertinent image data; customized side-by-side image comparisons; and image reorganization, for example.

FIG. 2 illustrates an example embodiment of a medical diagnostic system that includes an abnormality-summary window 200. Abnormality-summary window 200 provides a convenient patient information summary 210 and an interface to import or enter additional data. In window 200 the radiologist can enter abnormality data for either the left or right breast by clicking on an "Add Abnormality" button 220. Additionally, a user can import a CAD report detailing any abnormalities that have been detected by existing CAD software. Examples of suitable CAD software include the Cad-Stream product by Confirma and the B-CAD product by Medipattern, among others.

As shown in FIG. 3, imported CAD information stored in compliance with a pre-determined system such as BI-RADS can be used to generate a wire-frame map or guide 230 depicting the location and depth of a ROI in or on a patient's anatomy that was detected by the CAD software or entered manually by a radiologist. The density of the patient's tissue is also presented in selector 240. The guide 230 includes both a craniocaudal (CC) view 250 and a mediolateral/oblique (ML) view 260 of both the left and right breasts of a patient. The ROI is depicted by the craniocaudal mark 252 and the mediolateral mark 262. In other situations, an abnormality may only be visible in one or the other of the ML or the CC view and, accordingly, only a single mark would be displayed in either the craniocaudal (CC) view 250 or the mediolateral/oblique (ML) view 260.

In an embodiment, the ROI data underlying either craniocaudal mark 252 or mediolateral mark 262 can be represented as the number of pixel spaces from at least two edges of the original image represented by the ROI. The retention of the number of pixels from at least two edges provides for the derivation of the location of the ROI on the original image. This allows the storage of multiple ROI for a single highresolution image without the need to store multiple copies of the high-resolution image or even high-resolution clippings. It also permits derivation or mapping of an ROI in one image to other images based on known pixel sizes and edge dis-

In another alternative embodiment, the data underlying these two marks are used to then calculate an approximate location of the abnormality as viewed by a physician when facing the patient. This calculation also compensates for the fact that during the creation of a mammography image, the patient's breast is compressed to increase the amount of viewable tissue in the two-dimensional x-ray image. Additionally, compensation must be made for the angle at which the mediolateral/oblique view 260 is taken relative to the craniocaudal view 250 during mammogram imaging. Those skilled in the art will appreciate that the two views are not necessarily created at angles exactly perpendicular to each other due to the wide variety of patient anatomy and the need to capture as much tissue as possible in each image. The breast orientation, size and thickness information is provided along with the mammogram image. The resulting combination of the craniocaudal data and the mediolateral data produce the clockposition 270 as shown for the exemplary ROI. This calcula-

tion is not calculated if the ROI is only visible on a single image, as both a craniocaudal and mediolateral position are required, along with a distance either from the patient's nipple or chest wall, to calculate the location of the ROI in three-dimensional space.

An abnormality does not need to be located or seen in both views to be characterized. Often in mammography an abnormality is only seen in one view and additional imaging is conducted to confirm its location in another view. The additional imaging can also reveal superimposed tissue, a situation in which the breast tissue of several layers was compressed together causing a potential mass seen in a single image with the appearance of an actual abnormality. A radiologist viewing multiple images of the same tissue area can appropriately categorize these situations.

Also shown in FIG. 3 is a three-word indication 272 of the approximate location of the ROI in the patient's breast. In this example the ROI is located in the inferior (lower), lateral (outside), middle (distance between the chest and nipple) portion of the patient's right breast. Similar terms for the 20 remaining quadrants and depth are provided by the ACR guidelines and will be understood by those skilled in the art.

An additional feature of the system is the capability of importing any ROI from a patient's previous examination that are already present in the system's database. A radiologist or 25 technician can select the "Clone Prey" button **280** to review and import data from a previous examination. This feature further eliminates the need for duplicated effort on the part of the medical professional conducting the review of the patient's exam images.

The system is capable of handling a variety of imaging technologies. FIG. 4 depicts an exemplary x-ray generated mammogram image 300 with an ROI indicated by a dashed outline 310 on the image 300 of the patient's breast tissue 320. FIG. 5 depicts an exemplary ultrasound image 330 with 35 an ROI indicated by a dashed outline 340 on the image 330 of the patient's breast tissue 350. While the type of information depicted in a mammogram image 300 is clearly different from the ultrasound image 330, the system maintains the ROI indicated on each respective image by storing the coordinates 40 of each ROI as an offset, in one embodiment utilizing the number of pixels, from at least two edges of the original digital image, regardless of the technique employed to generate the image. These coordinates are then used to calculate the distance from the patient's chest wall, nipple, or other 45 appropriate reference point, to determine the measurements defining the location of the ROI. Similar techniques can be applied to other imaging technologies such as MRI or CT images that are capable of being stored in a standardized digital format where the correlation of the number of pixels in 50 the image to the real-world distance depicted in the image is known.

FIG. 6a depicts an embodiment of an abnormality-detailing window 400. The detailing window 400 provides an interface for a radiologist to enter or view the detailed attributes 55 that describe an abnormality in a selected ROI. FIG. 6a depicts the single attribute 402 of a "Mass" as being selected to describe the ROI depicted in FIG. 3. As indicated by the system, the presence of a mass alone is generally not enough to indicate the presence of a malignancy. The radiologist then 60 selects an impression 404 and an appropriate recommendation in the "Impression & Recs" area 406. In one embodiment, the system suggests an impression or recommendation in area 406 based on other selected attributes in window 400, which can then be reviewed by the radiologist and altered, if 65 desired. The system can also dynamically and automatically adjust the selection in area 406 if other attributes in window

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400 are changed during review. In other embodiments, area **406** is selectable by a radiologist or doctor.

The abnormality-detailing window 400 can include a profiler button 410 that provides a count of matching abnormalities and their pathological outcome. The profiler button 410, or another appropriate window, displays the number of biopsies performed that were diagnosed as malignancies 412, the number of biopsies performed that were diagnosed as benign 414, and the total number of matching abnormalities 416 in the database. The sum of the number of malignancies 412 and the number of benign 414 is the total number of biopsies performed on abnormalities possessing the same attributes selected in detailing window 400 at that location. The second line 418 of profiler window 410 displays these same quantities found in a national database. As discussed above, the single attribute of a Mass 402 in FIG. 6a yields a relatively low number of malignancies 412 (roughly 1.4%) of similar abnormalities in the local database. The combination of the number of malignancies 412 and the number of benign 414 is also a low percentage of the total number of similar abnormalities, indicating a low frequency of requests by the patient's physician for a biopsy. The profiler button 410 is depicted in the lower corner of the screen to provide a convenient, yet out of the way area to present statistical information. Other locations or embodiments, such as a floating window that can be repositioned by the radiologist are contemplated.

Two database versions are typically present in every system—one is the "local" version containing the data specific to the medical facility where the system is installed. This local data can be subsequently uploaded to a centralized server to be integrated with into a "regional," "national," or "global" version of the database. This allows individual users to compare their own facility's results with a larger sample of results. Additionally, the "local" version can be linked to the on-site examination image data, allowing the radiologist to see other examinations related to a specific pathology finding or set of characteristics. The radiologist can then nearly instantly view selected examinations, images, or specified regions of interest retrieved from the local database. The system can also be configured to link to information and retrieve images from the larger databases, although in one embodiment this can be done without any patient identifying information.

FIG. 6b depicts the abnormality-detailing window 400 of FIG. 6a, with three additional characteristics that describe the ROI. The Mass 402 is characterized as "Irregular" 420, "Microlobulated" 422, and having a "High density" 424. In the "Impression & Recs" area 406 the addition of the "5 Highly suggestive" 426 attribute indicates that a follow-up examination of the patient is necessary. In this case, the radiologist has selected the "Ultrasound guided bx" option 428, indicating that the recommended next step for the patient is an ultrasound-guided biopsy of the abnormality.

The addition of the three ROI characteristics in FIG. 6b significantly narrowed the number of matching abnormalities in the MIS database as shown in the profiler button 410. While only half of the biopsied abnormalities resulted in a result of malignancy 412 for the local database, as seen in the national database line 418, the vast majority of biopsied abnormalities of this type were malignant. While the relatively low number of data points presented for this abnormality type may not be sufficient to draw any definitive conclusions, this example shows the utility of being able to compare a local sample with a larger multi-site database of abnormalities providing an indication to the local medical personnel that further review of this abnormality scenario may be required. Those skilled in

the medical and radiology arts will appreciate these and other advantages that this collection of data and the ease of access provided by the system yield.

FIG. 6c depicts another example of a right breast MRI abnormality-detailing window 440 and an example of an MRI abnormality-dimensioning window 442. These two windows display the BI-RADS compatible data points, optionally generated by a CAD software package used to pre-evaluate and generate the ROI in the MIS. In one embodiment, the CAD software package can populate the various fields presented by an abnormality window, such as exemplary MRI abnormality-dimensioning window 442. These widows also provide a radiologist with an interface to adjust, re-characterize, correct, or remove the ROI data based on their professional assessment of the ROI depicted in the patient's images. As depicted, in abnormality-dimensions window 442 a radiologist can quickly select or change the radial size, anti-radial size, transverse size, AP size, cranio size, distance from the nipple, distance from the skin, and distance from the chest, of the abnormality. Other appropriate measurements or mechanisms for entering these values are also contemplated.

The system contemplated in the example embodiment dynamically updates the values shown in the profiler button **410**, of FIG. **6**b, every time a new attribute is selected in abnormality-detailing window 400. One embodiment can achieve this high access speed by assigning an enhanced version of ACR lexicon descriptors to individual bits in a group of integers. This approach also yields a relatively compact database size, further minimizing search time. The tables below provide an exemplary sampling of potential abnormality lexicons. Each item in a lexicon is assigned a value. In Table 1, the STATS VALUES field first provides a specified index into a list of database field values. These database fields are assigned indexes numbered 0 to n-1. The second hexadecimal value is the actual value assigned to the individual lexicon item. When this item is selected during an examination, the specified bit value is set in the assigned integer field using a bitwise OR operation. The LISTBOX_NAME column provides the general description of where on the abnormality-detailing window 440 the attribute would be grouped. The ITEM NAME column provides the detailed characteristic that a radiologist can select when characterizing a patent image.

TABLE 1

Mammogram Lexicon Item Detailing				
LISTBOX_NAME	ITEM_NAME	STATS_VALUES		
Specify Abnormality	Fibrocystic tissue	0,0x00000001		
Specify Abnormality	Cyst simple	0,0x00000002		
Specify Abnormality	Mastitis area	0,0x00000004		
Specify Abnormality	Mass solid	0,0x00000008		
Specify Abnormality	Lesion	0,0x00000010		
Specify Abnormality	Cyst	0,0x00000020		
Specify Abnormality	Abscess	0,0x00000040		
Specify Abnormality	Mass	0,0x00000080		
Specify Abnormality	Papillary lesion	0,x000000100		
Profile Abnormality	Irregular	1,0x00000001		
Profile Abnormality	Lobulated	1,0x00000002		
Profile Abnormality	Oval	1,0x00000004		
Profile Abnormality	Reniform	1,0x00000008		
Profile Abnormality	Round	1,0x00000010		
Profile Abnormality	Circumscribed	1,0x00000020		
Profile Abnormality	Microlobulated	1,0x00000040		
Profile Abnormality	Obscured	1,0x00000080		
Profile Abnormality	Indistinct	1,0x00000100		
Profile Abnormality	Spiculated	1,0x00000200		
Profile Abnormality	Intraductal	1,0x00000400		
Profile Abnormality	Irregular	1,0x00000800		

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TABLE 1-continued

			ogram Lexicon Item Detailing		
	LISTBOX_NAME	ITEM_NAME	STATS_VALUES		
	Profile Abnormality	Smooth	1,0x00001000		
	Profile Abnormality	High density	1,0x00002000		
.0	Profile Abnormality	Equal density	1,0x00004000		
	Size and Distance	Parallel/skin	1,0x00800000		
	Size and Distance	Perpendic/skin	1,0x01000000		
	Assoc Calcs	Generic calcs	2,0x00000001		
	Assoc Calcs	Amorphous	2,0x000000002		
	Assoc Calcs	Branching	2,0x000000004		
	Assoc Calcs	Coarse	2,0x000000008		
	Assoc Calcs	Dystrophic	2,0x00000010		
	Assoc Calcs	Eggshell	2,0x00000020		
	Assoc Calcs	Lucent-centered	2,0x00002000		
	Assoc Calcs	Milk of calcium	2,0x00004000		
	Assoc Calcs	Pleomorphic	2,0x00008000		
	Assoc Calcs	Punctate	2,0x00010000		
	Assoc Calcs	Rim	2,0x00020000		
	Assoc Calcs	Round	2,0x00040000		
0	Assoc Calcs	Skin	2,0x00080000		
	Assoc Calcs	Spherical	2,0x00100000		
	Assoc Calcs	Suture	2,0x00200000		
	Assoc Calcs	Vascular	2,0x00400000		
	Assoc Calcs	Clustered	2,0x00800000		
	Assoc Calcs	Diffuse	2,0x01000000		
	Assoc Calcs	Grouped	2.0x02000000		
	Assoc Calcs	Linear	2,0x04000000		
	Assoc Calcs	Regional	2,0x08000000		
	Assoc Calcs	Scattered	2,0x100000000		
	Assoc Calcs	Segmental	2,0x20000000		
	Associated findings	Hematoma	3.0x00000001		
	Associated findings	Nipple retract	3,0x00000001		
	Associated findings	Seroma	3,0x00000002		
	Associated findings	Skin involvement	3,0x000000000		
	Associated findings Associated findings	Skin lesion	3,0x00000010		
	Associated findings Associated findings	Skin retraction	3,0x00000020		
	Associated findings Associated findings	Skin thicken	3,0x000000040		
	Associated findings Associated findings	Trab thicken	3,0x000000000		
	Change From Prior	Incr in size	3.0x00000100		
	Change From Prior	Decr in size	3,0x00000200		
		Incr in calcs	3,0x00000400		
	Change From Prior Change From Prior	Decr in cales	3,0x00002000 3,0x00004000		
		Incr in number	3,0x00004000 3,0x00008000		
	Change From Prior		,		
	Change From Prior	Decr in number	3,0x00010000		
1 0	Change From Prior	Less prom.	3,0x00020000		
	Change From Prior	More prom.	3,0x00040000		
	Associated findings	Archit distortion	3,0x00080000		
	Associated findings	Axillary adenop	3,0x00100000		
	Associated findings	Chest wall invas	3,0x002000000		

The database of ROIs created from all examinations, detailed abnormalities, and pathology is generated and electronically stored at one or more sites. The information is then concatenated. As each exam and abnormality's result is created using the bitwise technique mentioned above, a search is made for an identical pathology finding with the identical set of bitset integer values (lexicon items) describing the abnormalities. If not found, a single record is created for each final abnormality pathology finding for each unique set of integer "lexicon" values. When duplicates are found, abnormality, benign, and malignant, the appropriate counters are incremented and the data displayed in profiler button 410 is updated.

In querying the database, the user selects lexicon items and/or pathology findings and the statistical system will instantly show "quick" statistics (total #'s only) in profiler button 410 for other exam abnormalities that "include" the profile of selected items. When the radiologist selects "round shape" he will instantly see statistics for all other abnormalities with a "round shape," noting how many were ultimately benign, how many were malignant, and how many were never biopsied. The radiologist can also view a statistical list of

findings for all abnormalities with "round shape," perhaps helping determine probabilities for malignancy. If the radiologist subsequently also selects "spiculated margin," the same process will occur for all abnormalities with a "round shape" AND a "speculated margin."

An example embodiment can use a bit-setting method to produce a typical database that is small enough such that it can be loaded into the main memory of the MIS to enable rapid retrieval and updates. In an embodiment, the loading process is performed by a background thread during system startup allowing the user to continue working during loading. In querying the database, all the system needs to do is convert the currently selected lexicon items into their corresponding bitmap values, and then search the database using an "exclusive OR" (xor) comparison on the database records. A record matches when all the "set" bit values from the selected items are "set" in the database record being compared. Abnormality, Benign, and Malignant counts on each matching record are tabulated and ultimately presented to the radiologist.

The combination of the high-speed statistical comparison database and the ROI image database allows an embodiment of the system to provide a radiologist with images stored at a local facility for comparative diagnostic purposes. The system also allows a radiologist to select images based on the BI-RADS or other lexicon abnormality descriptors, allowing a comparison of additional images from a larger database or final pathology results if the abnormality was biopsied. Table 2 provides on exemplary mapping of BI-RADS values to the more efficiently stored and searched bit-field values.

TABLE 2

Mammogram Lexicon to BIRADS Conversion and Detailing				
ABNORMALITY	CLASSIFICATION	DESCRIPTOR ID NUMBER		
Mass	Irregular	16	0x000000001	
Shape	Lobulated	190	0x00000002	
•	Oval	15	0x00000004	
	Reniform	27	0 x 000000008	
	Round	14	0x00000010	
Margin	Circumscribed	109	0x00000020	
_	Microlobulated	111	0x00000040	
	Obscured	28	0x00000080	
	Indistinct	21	0x00000100	
	Spiculated	29	0x00000200	
	Intraductal	201	0x00000400	
	Irregular	20	0x00000800	
	Smooth	18	0x00001000	
Density	High density	211	0x00002000	
	Equal density	213	0x00004000	
	Low density	212	0x00008000	
	Fat containing	214	0x00010000	
	Cent lucent	215	0x00020000	
Wall	Septated internal wall	25	0x00080000	
	Irregular internal wall	24	0x00100000	
	Smooth internal wall	23	0x002000000	
	Thickened wall	199	0x00400000	
Calcification	(generic calcs)	701	0x00000001	
Type	Amorphous	702	0x000000002	
	Branching	703	0x00000004	
	Coarse	704	0x000000008	
	Dystrophic	705	0x00000010	
	Eggshell	706	0x00000020	
	Fine	707	0x00000040	
	Heterogeneous	708	0x00000100	
	Indistinct	709	0x00000200	
	Large rodlike	710	0 x 00000400	
	Layering	711	0x00000800	
	Linear	712	0x00001000	
	Lucent-centered	713	0x00002000	
	Milk of calcium	714	0 x 00004000	

TABLE 2-continued

	Mammogram Lexicon to BIRADS Conversion and Detailing				
5	ABNORMALITY	CLASSIFICATION	DESCRIPTOR ID NUMBER		
		Pleomorphic	715	0x00008000	
		Punctate	716	0x00010000	
10		Rim	717	0x00020000	
		Round	718	0x00040000	
		Skin	719	0x00080000	
		Spherical	720	0x00100000	
		Suture	721	0x00200000	
		Vascular	722	0x00400000	
	Calcification	Clustered	751	0x00800000	
15	Distribution	Diffuse	752	0x01000000	
13		Grouped	753	0x02000000	
		Linear	754	0x04000000	
		Regional	755	0x08000000	
		Scattered	756	0x10000000	
		Segmental	757	0x20000000	
	Foreign body,	Hematoma	478	0x00000001	
20	Scar, or other	Nipple retract	477	0x000000002	
	(typically ignore)	Post surgical scar	479	0x00000004	
		Seroma	469	0x000000008	
		Skin involvement	252	0x00000010	
		Skin lesion	473	0x00000020	
		Skin retraction	251	0x00000040	
25		Skin thicken	250	0x00000080	
		Trab thicken	470	0x00000100	
	Changes from	Incr in size	77	0x00000200	
30	prior exam	Decr in size	78	0x00000400	
	•	Incr in calcs	483	0x00002000	
		Decr in calcs	484	0x00004000	
		Incr in number (mass)	481	0x00008000	
		Decr in number (mass)	482	0x00010000	
		Less prom.	293	0x00020000	
		More prom.	294	0 x 00040000	

Detailing window **400** displays information that can be stored as BI-RADS compatible data points, or another suitable lexicon. Optionally the ROI data can be generated by a CAD software package used to pre-evaluate and categorize the ROI in the MIS. Detailing window **400** also provides a radiologist with an interface to adjust, re-characterize, correct, or remove the ROI data based on their professional assessment of the ROI depicted in the patient's images if they radiologist disagrees with the CAD generated results. All of this information can be stored in a database configured to correlate all of a patent's ROI data and images.

The features provided by the system can also be combined with any one of several available computer aided diagnostic (CAD) products to validate, improve, and allow simplified testing of future CAD algorithms. A CAD product can be evaluated by using the electronically compiled descriptions of any abnormalities shown in a collection of ROI images to compare the CAD software algorithms against the real world pathology or biopsy results that were actually performed on the ROIs depicted in the image database.

Once the reliable performance of a CAD algorithm is established it may be used to further assist or confirm radiologist assessments of mammography images from new patients, or to alert the medical staff or radiologists when new or previously unclassified abnormalities are detected. Additionally, the integration of a CAD algorithm and the lexicon abnormality descriptors to generate ROI entries, such as those depicted in FIG. 6b, can pre-select the ROI classifications for each abnormality detected by a CAD product. This combination is especially advantageous as it reduces the number of radiologist provided entries to only corrections to the CAD interpretation of an ROI or any ROI that were not categorized initially by the CAD product. While a handful of mouse clicks

or keyboard entries, or similar gestures, may seem trivial, the combined time savings over the high volume of patient images that must be reviewed can yield a substantial savings in time, cost and comfort.

In the example embodiment discussed above, the display of the statistical results in profiler button 410 is automatically updated every time the radiologist enters or changes a data point. In another embodiment, the statistical results display window or profiler button 410 is hidden, or the update suppressed, until the entry of all of the patient's data is complete. This alternative embodiment may be useful as a training tool for educating new radiologists by preventing them from being influenced by the statistical updates as they perform their entry of the data points for a patient.

As shown in FIG. 7, when the user activates, or clicks on, 15 the profiler button 410 of FIG. 6b, a window of matching statistical information 500 is displayed. This window of matching statistical information 500 includes the individual quantity 502 and the percentages 504 for malignant and benign outcomes in a sorted itemized list with both local and 20 national data based on the matching selected abnormality features. Additionally, window 500 also includes the various pathology findings 506, as well as the code for that finding 508, contained in the database.

The example embodiment provides a "show exams" button 25 510 that allows a radiologist to retrieve the examinations for an individually selected pathology type 512. FIG. 8 depicts an examination list window 550 for the selected pathological type 512. The matching exams displayed in FIG. 8 are only those database records from the local facility database. Any records retrieved from a non-local database would not contain any patient identifying information. The embodiment of the MIS depicted here further provides the radiologist with the opportunity to select a record 560 of individual patient with the same diagnosis 512 for further review. The selection of the 35 "View patient priors" button 570 directs the system to open a window containing the selected patient's examination record and "Send Images to Viewstation" button 572 that can be selected to send images to display workstation 100 or image monitors 112 and 114 that allows the radiologist to view 40 multiple matching imaging features and pathological outcomes in similar imaging modalities.

FIG. 9 depicts an exemplary prior exam window 600 displaying the images for an individual patient's exam. Prior exam window 600 includes existing or historical exam 45 images for the selected patient for referencing process of care. By selecting an individual exam report 602 and then one of the "View Full" 604, "Preview" 606, "Print" 608, or "Send to Viewstation" 610, the radiologist can examine the selected exam report 602 and optionally compare the images contained in that record to the current patient's images. Additionally, the system allows the radiologist to export a variety of bulk data, such as to a CD or other location with the "Create CD" button 612 option. The bulk data may include all of the images related to a single patient or a collection of categorized abnormality images that match a set of selected abnormality attributes or some other data subset.

FIG. 10 depicts a patient report 700 summarizing the details of the CAD or radiologist findings from the examination and analysis of the patient's images. The report 700 can 60 contain a clipped portion of the medical image or a thumbnail picture summarizing the ROI, as well as a multi-perspective wireframe guide that maps the location of the ROI onto the outline of the patient's anatomy.

FIG. 11 through FIG. 14 depict an exemplary embodiment 65 of a standalone or web-based interface 800 to an embodiment of the profiler system. The web-based interface 800 can be

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accessed with any of the commonly available web browsers such as Microsoft Internet Explorer or Mozilla Firefox. As appreciated by those skilled in the art, a web-based interface may be hosted on a server connected to the Internet for use by a variety of geographically separated individuals or locally where access is limited to a particular facility's local network.

FIG. 11 depicts a web-based interface 800 providing a mechanism to select various characteristics regarding abnormality information contained in a database. Four modalities are presented, Mammogram—Mass 802, Mammogram—Calcification 804, MRI 806 and Ultrasound (US) 808. Depending on the modality selected, additional characteristics related to the selected modality are displayed to provide further details of the abnormality information request. The example depicted in FIG. 11 indicates a request for abnormality information contained in the database where the abnormality is categorized as a Mammogram—Mass 802, has an irregular shape 810, a speculated margin 812, and a high density 814. Mammogram—Mass 802 can also have associated calcification types 818.

As depicted in FIG. 12, the Mammogram—Calcification 804 modality is selected as the primary abnormality, and the Mass column containing the Shape 810, Margin 812, Density 814, and Orientation 816 categories, shown in FIG. 11, are removed from the interface 800. Interface 800 can include a results summary display area 820 and a matching pathology display area 840. The results summary display area 820, in a manner similar to the profiler button 410 of FIG. 6a, displays a count of matching abnormalities and their pathological outcome that were found in the database, as well as the percentages of the biopsied abnormalities that we either malignant or benign.

The matching pathology display area 840 can include a list of findings that can detail the percentages of a pathology diagnosis for abnormalities that were malignant or benign. The display area 840 example includes the result 842 as either malignant or benign, the number of entries 844 in the national database, the percentage 846 that each pathology represents of either the malignant or benign diagnosis, a pathology code 848 and a summary of the finding 850. Both the results summary display area 820 and the matching pathology display area 840 are updated whenever a new abnormality categorization is selected.

FIG. 13 depicts an example embodiment of interface 800 displaying categories that are related to the MRI 806 modality. As shown in the "Percent of" column 852 of the matching pathology display area 840, the percentages of the abnormality diagnosis are calculated as the number of relevant diagnosis from the total number of just the malignant or just the benign results. As shown, the percentages of malignant diagnosis equal 100% and the benign diagnosis equal 100%.

FIG. 14 depicts an example embodiment of interface 800 displaying categories that are related to the ultrasound 808 modality. The ultrasound 808 modality includes fields for "Boundary," "Hilum," Echo," and "Internal Echo" in column 860 that are specific to ultrasound imaging techniques. It is contemplated that other fields, columns, or modalities can be added or presented as needed to accommodate the preferences of the user or to incorporate other new or existing diagnostic technologies.

FIG. 15 depicts an embodiment of a ROI Gallery 900 containing selected image clippings 910 that have been associated with the ROI depicted by the craniocaudal mark 252. The activation of the "Roi Gallery" button 290, shown in FIG. 3, causes the ROI Gallery 900 to be presented to the user. The image clippings 910 can be selected from any region of a medical image available to the radiologist on the MIS. A low

magnification image **912** can be useful to identify a large area of tissue. Alternatively, a smaller, higher magnification image **914** can provide the radiologist with greater detail.

The association of image clippings **910** can allow the radiologist to associate a variety of images with the set of categories, such as those associated with the ROI of FIG. **3**. By correlating a subset of a full resolution image the radiologist is able to focus on the specific area that is described by the characteristics. This correlation of ROI characteristics with any of a variety of radiologist selected image clippings **910** can then be used in during future examinations to quickly focus in on individual areas that may need review. One example would be clipping a view of an abnormality that the radiologist recommended be reviewed after six or twelve months for any changes in size or appearance.

Additionally, the system provides for the clipping of various modalities of images. In addition to the mammogram images as shown in the ROI Gallery 900, additional images such as ultrasound or MRI captures can also be included in the gallery. One embodiment of this system can employ the stor- 20 age of individual image clippings 910 in a compressed image format, such as the JPEG image format established by the Joint Photographic Experts Group, or another appropriate standard. The use of a compressed image format provides an acceptable resolution for a thumbnail image for an initial 25 investigation, while requiring less storage space than a highresolution image format, such as the DICOM format. The system also provides a link from the compressed image clippings 910 to the full-sized high-resolution image for the situations, such as making a diagnostic assessment, that require a 30 radiologist to view the high-resolution image.

In one embodiment of the system, a database of thumbnail or clipped images can provide a source of investigational data that may assist a radiologist in categorizing an abnormality that he or she is unfamiliar with, or for use as a training tool.

The association of the ROI categorizations with the clipped images also provides an efficient mechanism to search for individual image clippings 910 of a particular type of abnormality or to provide a convenient link to pathology reports or patient correspondence. Non-image based information such as patient correspondence or reports can be stored in the ROI Gallery 500 either in their native format or in an image format, such as JPEG, TIFF, GIF, or another appropriate standard, derived from a screen-capture of the report or document

FIG. 16a is another depiction of ROI Gallery 900. Image clipping 910, as well as other images, can be attached or associated directly to an abnormality, such as ROI, depicted by the craniocaudal mark 252. FIG. 16b depicts of ROI Gallery 900 with a single highlighted image clipping 910 as 50 indicated by highlight-bar 920. Various exemplary tools are shown in ROI Gallery 900 that provide for the manipulation of individual image clippings. When an image is associated to an abnormality, the title bar 920 changes color, indicating a direct association. Tapping the "+"924 provides a mechanism 55 to attach image to abnormality 910. Tapping "-" 926 disassociates image clipping 910 or tapping on magnification button 928 brings up an individual ROI viewer 950 to allow a large view along with access to other imaging tools.

Within the title bar the description of the view is displayed from the image it was obtained from, for example RCC (RightCranioCaudal) image. In an embodiment, if the image was processed through a CAD tool, the feature descriptors, such as CAD-generated ROI outlines provided by that tool, are displayed. In another embodiment, feature descriptors can be superimposed as an overlay on top of the image. Alterna-

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tively, a hovering tool bar tool, for example when a user leaves the mouse cursor over an image, provides a small message describing the area. Additionally, in order to reduce right/left errors when associating images to an ROI, the imaging gallery does not allow right ROI to be associated to left breast abnormality, and a left ROI is not allowed to be associated with a right breast image or abnormality.

As depicted, a user can delete 922 the image clipping 910, or open the image clipping 910 in an individual ROI viewer upon the selection of magnification button 928.

FIG. 17 depicts an example embodiment of a ROI viewer 950 depicting an individual image 952. The ROI viewer 950 provides additional image manipulation tools, including an "invert" selector 954 that replaces the black pixels for white and the white pixels for black. The ROI viewer 950 also provides a "3D" button 956 that can support the activation of a separate 3D-modeling software package, one example of which is available from Clario, that enables the radiologist to view and rotate a composite three-dimensional image of the associated ROI. The radiologist may return to the ROI Gallery 900 by selecting either the "Exit" button 958 or the "Close Window" icon 960.

FIG. 18 is an example of a patient work-list form 1000 for use with embodiments of this invention. The work-list form 1000 allows the system to coordinate the retrieval of any high-resolution images in order to effectively utilize network bandwidth and system storage capacity. FIG. 19 is an example of a prior examinations form 1100 for use with embodiments of this invention. The prior examination form 1100 provides a radiologist with convenient access to a patient's prior medical image for review or comparison with a more current set of images.

As shown by the preceding examples, the invention provides an integrated system and methods for the categorization, storage, retrieval, and correlation of a wide variety of patient data, diagnostic images from multiple imaging sources, test results, statistics and correspondence. The integration of a ROI profiler, a statistical analysis tool, and the gallery of clipped images, together with native high-resolution medical images provides radiologists and other medical professionals with a customizable tool that provides greater efficiencies while also improving the accuracy of patient diagnostic screenings.

The foregoing descriptions present numerous specific details that provide a thorough understanding of various embodiments of the invention. It will be apparent to one skilled in the art that various embodiments, having been disclosed herein, may be practiced without some or all of these specific details. In other instances, known components have not been described in detail in order to avoid unnecessarily obscuring the present invention. It is to be understood that even though numerous characteristics and advantages of various embodiments are set forth in the foregoing description, together with details of the structure and function of various embodiments, this disclosure is illustrative only. Other embodiments may be constructed that nevertheless employ the principles and spirit of the present invention. Accordingly, this application is intended to cover any adaptations or variations of the invention. It is manifestly intended that this invention be limited only by the following claims and equivalents

For purposes of interpreting the claims for the present invention, it is expressly intended that the provisions of Section 112, sixth paragraph of 35 U.S.C. are not to be invoked with respect to a given claim unless the specific terms "means for" or "step for" are recited in that claim.

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Any incorporation by reference of documents above is limited such that no subject matter is incorporated that is contrary to the explicit disclosure herein. Any incorporation by reference of non-priority documents above is further limited such that no claims included in the documents are incorporated by reference herein and any definitions provided in the documents are not incorporated by reference herein unless expressly included herein.

The invention claimed is:

- 1. A configurable mammography diagnostic system, comprising:
 - a plural of electronic displays, at least one of the plurality of electronic displays configured to display a breast tissue image having at least one region of interest, the breast tissue image having an imaging modality of at 15 least one of radiological, X-ray, computed tomography, ultrasound, magnetic resonance, or tomosynthesis, wherein a computer aided diagnostic (CAD) tool selected based on the imaging modality is configured to identify the at least one region of interest:
 - a first networked database including a plurality of existing categorizations of at least one known region of interest in at least one of a plurality of breast tissue images for a medical facility;
 - a second networked databases including a plurality exist- 25 ing categorizations of at least one known region of interest in at least one of a plurality of breast tissue images for a plurality of medical facilities;
 - a graphical user interface presented on at least one of the plurality of electronic displays and including:
 - an anatomical diagram on which the at least one region of interest can be marked,
 - a detailing button linked to a screen configured to present a plurality of possible characteristics according to which a manual current categorization of a 35 region of interest in the breast tissue image can be defined, and
 - a profiler display button configured to present an adjacent display of statistical information from a comparison of the manual current categorization with the 40 existing categorizations of the first networked database and the second networked database, wherein the statistical information comprises: a number of biopsies performed that were diagnosed as malignancies; a number of biopsies performed that were diagnosed 45 as benign; and a total number of matching abnormalities:
 - a clipping tool with which a portion of the breast tissue image displayed on at least one of the plurality of electronic displays can be selected as a second image, the 50 second image displayable on at least one of the plurality of electronic displays as a subset of the breast tissue
 - a processing engine configured to link the second image to the breast tissue image, store the second image in an 55 image database, and to associate the second mage with a corresponding region of interest marked on the anatomical diagram.
- 2. The System of claim 1, wherein each of the plurality of breast tissue images is cataloged in the first or second net- 60 worked database according to a characteristic of the breast tissue image.
- 3. The system of claim 2, wherein the characteristic is the existing categorization.
- 4. The system of claim 1, wherein the CAD tool is operable 65 to detail the potential region of interest to provide a CAD current categorization.

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- 5. The system of claim 4, wherein the processing engine is operable to compare the CAD current categorization and the manual current categorization determined for a particular region of interest.
- 6. The system of claim 5, wherein an algorithm of the CAD tool is updated based on the comparison of the CAD current categorization with the manual current categorization.
- 7. The system of claim 4, wherein the processing engine is operable to compare the CAD current categorization with pathological data related to a particular region of interest.
- 8. A computer-implemented method for managing patient mammography data comprising:
 - obtaining, by a networked computer system, a plurality of breast tissue images, according to an imaging modality, wherein the imaging modality is at least one of an X-ray image, a CT image, an MRI image, at ultrasound image, and a pathology image;
 - selecting a computer aided diagnostic (CAD) module based on the imaging modality;
 - identifying, with the CAD module, a region of interest in at least one of the plurality of breast tissue images;
 - obtaining a categorization of a breast tissue abnormality in the region of interest according to an established lexi-
 - comparing, by the computer system, the categorization with a first database of existing categorizations of a medical facility and a second database of existing categorizations of a plurality of medical facilities and presenting, by the computer system, as diagnostic indicator based on the comparing, wherein presenting comprises adjacently displaying a number of biopsies performed that were diagnosed as malignancies; a number of biopsies performed that were diagnosed as benign; and a total number of matching abnormalities for the existing categorizations of both the first database and the second database:
 - storing, by the computer system, a selected region of the at least one of the plurality of breast tissue images as a second image;
 - mapping, by the computer system, the second image to storage location of the at least one of the plurality of breast tissue images; and
 - associating, by the computer system, the selected region with the categorized region of interest.
- 9. The computer-implemented method of claim 8, further comprising altering the categorization, and updating, by the computer system, the diagnostic indicator based on a Comparison of the altered categorization and the existing categorizations.
- 10. The computer-implemented method of claim 8, wherein presenting, by the computer system, the diagnostic indicator comprises presenting a number of instances at the categorization within the existing categorizations, a number of diagnoses of malignant abnormalities for the categorization among the existing categorizations, and a number of diagnoses of benign abnormalities for the categorization among the existing categorizations.
- 11. The computer-implemented method of claim 8, further comprising cataloging, by the computer system, images in the database according to at least one characteristic of the categorization or the existing categorizations.
- 12. The computer-implemented method of claim 8, wherein obtaining a categorization comprises obtaining a human categorization.
- 13. The computer-implemented method of claim 12, further comprising comparing, by the computer system, the

human categorization with a computer aided diagnosis (CAD) categorization for the same region of interest.

- 14. The computer-implemented method of claim 8, wherein the database of existing categorizations includes an identified region of interest in each of a plurality of breast 5 tissue images, and wherein each region of interest is associated with one of either a malignant or al benign diagnosis.
- 15. The computer-implemented method of claim 14, further comprising comparing, by the computer system, the associated malignant or benign diagnosis of a region of interest in the database with a computer aided diagnosis (CAD) of the one of the plurality of breast tissue images associated with the region of interest.
- **16**. The computer-implemented method of claim **8**, wherein obtaining a categorization comprises obtaining a 15 computer aided diagnosis (CAD) categorization.

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